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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 200403

Application Number: 08/323,060
Filing Date: October 14, 1994
Appellant(s): COMP, PHILIP C.

Patrea Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/4/2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct except that claims 7-9,20,21 are allowed in view of the amendment filed 12/4/2003.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct except that the amendment after final filed 12/4/2003 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims stand or fall together. It is noted that "11-3" should read "11-13".

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-6,11-13,19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the "inhibitor of an anticoagulant" as recited in the claims.

The instant claims encompass a method that uses an "inhibitor of an anticoagulant" wherein the anticoagulant is recited in the claims. However, the only "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) disclosed in the specification is an antibody which binds the anticoagulant recited in the claims. The specification refers to undisclosed chemical inhibitors without identifying said agents. The claims encompass a vast genus of potential agents which could function as an "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) while only disclosing antibodies which have that function. The claims could potentially encompass the use of agonist peptides or mimotopes with the functional properties recited in the claim, but there is no disclosure of such agents in the specification. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of

DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the

sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

(11) Response to Argument

Claims 1-6,11-13,19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons stated in section (10).

Regarding appellants comments in page 8 of the instant Brief, method claims require the same degree of written description under 35 USC 112 first paragraph as product claims. Furthermore, for the reasons enunciated below, the only inhibitors of an anticoagulant known at the time of the effective filing date of the instant application were antibodies.

Appellant has referred to a variety of different references (pages 9 and 10 of the instant Brief) that were published **after the effective filing date of the instant application** (eg. 7/24/1992, wherein the instant application is a FWC of parent application 07/919219 filed 7/24/1992). These references are not germane to the instant rejection because they reflect the state of the art **after the effective filing date of the instant application**. Regarding the analysis for compliance with written

description under 35 U.S.C. 112, first paragraph, the MPEP section 2163, section 2 (page 2100-164 Rev. Feb. 2003) states

The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art ***at the time the application was filed*** *(see, e.g., Wang Labs. v. Toshiba Corp., 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).*

Thus, the references published in 1993 and 1994 cited in page 9 of the Brief and those published after the effective filing date of the instant application (e.g. Thromb. Haemost.,1992(3):310-314) are not relevant to the instant rejection because they disclose the state of the art after the effective filing date of the instant application.

Regarding appellants comments, the instant claims encompass a method that uses an "inhibitor of an anticoagulant" wherein the anticoagulant is recited in the claims. However, the only "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in

the claims) disclosed in the specification is an antibody which binds the anticoagulant recited in the claims. The specification, pages 12 and 13 refers to undisclosed chemical inhibitors without identifying said agents. The claims encompass a vast genus of potential agents which could function as an "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) while only disclosing antibodies which have that function. The claims could potentially encompass the use of agonist peptides or mimotopes with the functional properties recited in the claim, but there is no disclosure of such agents in the specification. It is noted that even if all of the references cited in pages 9 and 10 of the Brief were considered, all but one of said references are drawn to use of antibodies against the inhibitors recited in the claims. The Examiner has already stated that such antibodies were known and described in the prior art. The single non-antibody reference is the Gene 1993 publication which ***does not describe an inhibitor of an anticoagulant***. It describes an inhibitor of a **coagulant**, not an anticoagulant. The specification does not disclose said publication or use of the methods of said publication to produce an inhibitor of an anticoagulant. Thus, appellant has not disclosed a single example of an art known inhibitor of an anticoagulant other than an antibody. Also as previously mentioned, the Gene 1993 reference was **not even published until after the effective filing date of the instant invention.**

While the instant application provides written description of antibodies which bind the anticoagulant molecules recited in claim 1, the claims encompass a vast genus of undisclosed inhibitors of said molecules. Regarding appellants comments, the only

specific inhibitor of one of the molecules disclosed in the claims that is disclosed in the specification is an antibody. The references cited by appellant that are pertinent to the instant rejection (eg. published before effective filing date of the instant application) also fail to describe any molecule other than antibody which would function as an inhibitor of the anticoagulants recited in the claims. While the anticoagulants recited in the claims are known in the art, their inhibitors other than antibodies are not described in the specification or the prior art. The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

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March 7, 2004

Conferees

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